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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,820	11/02/1999	ARCHANA KAPOOR	A-57004-4/RF	1595

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/432,820

Applicant(s)

KAPOOR ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,26-33,41-50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,26-33,41-50 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-29-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 1-29-04.

Claims 24, 26-33, 41-50 and 52 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claims 24, 26-33, 41-49 and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the Office action mailed January 30, 2001, Paper No. 9. This rejection was withdrawn in the Office action mailed 8-25-03, but has been reinstated upon further consideration because the term *antigenic determinant*, as it pertains to SEQ ID NO: 2, has not been adequately described in the instant disclosure or in the art. The rationale for reinstating this rejection is elaborated below.

Applicant's arguments filed 6-17-03 and 5-9-02 have been fully considered but they are not persuasive. Applicants argue that antibodies reactive against SEQ ID NO: 2 are specific because tuberculosis patients' sera recognize a single protein band (i.e.

of apparent molecular weight of 90kDa as illustrated by western blotting in figure 3 of the instant specification). Applicants argue further that because of this specific recognition, combined with the purported topology of the polypeptide deduced from the amino acid sequence of SEQ ID NO: 2 (e.g. figure 5 of the instant specification), as well as the failure to hybridize non-infectious Mycobacterial strains (*M. smegmatis* and *M. vaccae*) by southern blotting under stringent hybridization conditions (figure 6), using a probe of the nucleic acid (i.e. SEQ ID NO: 1) encoding the polypeptide of SEQ ID NO: 2, the written description requirement for the antigenic determinant of SEQ ID NO: 2 has been properly satisfied. Contrary to Applicants' assertions, the generation of a single band by western blotting of the entire sequence of SEQ ID NO: 2 does not particularly or adequately describe what portion of this sequence is the antigenic determinant recognized by the antibodies present in the patients' sera. Likewise, the purported topology of the intramembraneous polypeptide of SEQ ID NO: 2 does not adequately describe what portion of the polypeptide is providing the antigenic determinant. The western blotting was performed on cell lysates, and the antigen providing the signal by western blotting might be derived from a membrane fraction with a cytosolic facing antigenic determinant, an intracellular facing antigenic determinant, or a partially solubilized, membrane-embedded, antigenic determinant. There is no way of distinguishing between these three possibilities (e.g. no intact cellular binding assays were provided to compare the antigenicity with the membrane topology of SEQ ID NO: 2), nor of determining what subsequences of the SEQ ID NO: 2 provide the antigenic determinant recognized by the antibodies of patients' sera. The lack of cross

Art Unit: 1635

hybridization by southern of a probe from the nucleotide sequence encoding the polypeptide of SEQ ID NO: 2 with non-virulent Mycobacterial strains *M. smegmatis* and *M. vaccae* does not provide the missing information to adequately describe the amino acid subsequences of SEQ ID NO: 2 that comprise the antigenic determinant of that sequence that is recognized by the patients' sera. Therefore, the 112, first paragraph rejection for lacking adequate written description for the antigenic determinant of SEQ ID NO: 2 is maintained.

New Rejections

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: detecting antibodies bound to purified protein that is homologous to SEQ ID NO: 2 and that is obtained from a virulent strain of Mycobacteria. This step is essential since the claim is drawn to a method of detecting the presence of antibodies binding to a virulent Mycobacterium. In addition, the hybridization step set forth in the claim does not allow for binding and/or identifying the probe bound to a target.

Claim Objections

Claim 50 is objected to because, in line 2, "Mycobacteriam" is misspelled and should be replaced with --Mycobacterium--.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ
8-15-04

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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